FEB 18 2014

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K131898

1. Date of Submission: 12/30/2013

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd
Innovation First Road, Technology Innovation Coast
Zhuhai, Guangdong, 519085, China

Establishment Registration Number: 3007305624

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Patient Monitors

Proposed Device Common Name: AnyView A8, AnyView A6, AnyView A5, AnyView A3, Q2, Q3, Q4, Q5, Q6 and Q7

Classification:

Regulation No.	Classification Name	Product Code	Device Class
Main Code			
21 CFR 870.2300	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)	MWI	Class II
Subsequent Product Codes			
21 CFR 870.1025	Detector and Alarm, Arrhythmia	DSI	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	MLD	Class II
21 CFR 870.2300	Cardiac monitor (including cardiotachometer and alarm)	DRT	Class II
21 CFR 870.1130	Non-invasive blood pressure measurement system	DXN	Class II
21 CFR 870.1113	Blood pressure computer	DSK	Class II
21 CFR 880.2910	Clinical Electronic Thermometers – Temperature Monitor with Probe	FLL	Class II
21 CFR 870.2700	Oximeter, Pulse	DQA	ClassII
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	CCK	ClassII
21 CFR 868.1500	Enflurane gas analyzer	CBQ	ClassII
21 CFR 868.1620	Halothane gas analyzer	CBS	ClassII
21 CFR 868.1700	Nitrous Oxide gas analyzer	CBR	ClassII
21 CFR 868.1720	Oxygen gas analyszer	CCL	ClassII
21 CFR 882.1400	Electroencephalograph	GWQ	ClassII
21 CFR 870.2770	Impedance plethysmograph	DSB	ClassII

Intended Use Statement:

Patient monitors are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR), Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood

Pressure (IBP), Carbon dioxide (CO_2), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Cerebral State Index (CSI), Bispectral Index (BIS), Total Hemoglobin(SpHb), Carboxyhemoglobin (SpCO) and Methemoglobin(SpMet).

The arrhythmia detection, ST segment analysis only applied to a single adult patient.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician. It is not intended for helicopter transport, hospital ambulance, or home use.

5. Predicate Device Identification

Predicate Device 1
510(k) Number: K120193
Product Name: AnyView Patient Monitors
Manufacturer: Guangdong Biolight Meditech Co., Ltd

Predicate Device 2
510(k) Number: K072286
Product Name: Aspect Medical Systems BIS EEG VISTA Monitor System
Manufacturer: Aspect Medical Systems, Inc.

6. Device Description

The Patient Monitors consist of two parts, which are host units and function modules.

The host units of AnyView A Series Patient Monitors are available in four modules, which are AnyView A3, AnyView A5, AnyView A6 and AnyView A8, The units, themselves, did NOT collect any physiological data from the patient, which are collected by function modules and transmitted to the host unit. They shall be worked with the basic function module, EMS or MPS.

The host units of Q Series Patient Monitors are available in six modules, which are Q2, Q3, Q4, Q5, Q6 and Q7. These host units could complete the measurement of ECG, RESP, TEMP, SpO2, NIBP and IBP.

In addition, there are several extended function modules, which could be connected with the host units to complete the measurement functions, including TEMP, IBP, CO_2 Mainstream, CO_2 Sidestream, SpO_2 Nellcor, SpO_2 Masimo, AG Mainstream, AG Sidestream, ICG and CSM (CSI).

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

a) IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
b) IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
c) AAMI EC13:2002, Cardiac monitors, heart rate meters, and alarms;
d) AAMI SP10:2002/ A1:2003 (R) 2008, Manual, electronic or automated sphygmomanometers;
e) ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use;

8. Substantially Equivalent (SE) Conclusion

The following table compares the A Series / Q Series Patient Monitors to the predicate devices with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	MWI	MWI
Regulation Number	870.2300	870.2300
Subsequent Product Code	DSI / MLD / DRT / DXN / DSK / FLL / DQA / CCK / CBQ / CBS / CBR / CCL / GWQ / DSB	DSI / MLD / DRT / DXN / DSK / FLL /DQA / CCK / CBQ / CBS / CBR / CCL/ GWQ / DSB
Intended Use	Patient monitors are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR), Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation(SpO2), Pulse Rate (PR), Non-invasive Blood Pressure	The AnyView series patient monitors including models AnyView A8, AnyView A6, AnyView A5 and AnyView A3 are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR),

	(NIBP), Invasive Blood Pressure (IBP), Carbon dioxide (CO2), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Cerebral State Index (CSI), Bispectral Index (BIS), Total Hemoglobin(SpHb), Carboxyhemoglobin (SpCO), and Methemoglobin(SpMet), The arrhythmia detection, ST segment analysis is only applied to a single adult patient. The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician. It is not intended for helicopter transport, hospital ambulance, or home use.	Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation(SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Carbon dioxide (CO2), Anesthetic Gas (AG), Impedance Cardiograph (ICG) and Cerebral State Index (CSI). The arrhythmia detection, ST segment analysis is only applied to a single adult patient. The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician. It is not intended for helicopter transport, hospital ambulance, or home use.
Sterile	No	No
Single Use	No	No
Energy Source	AC Power / DC Power	AC Power / DC Power
Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Performance	Comply with AAMI EC13	Comply with AAMI EC13
	Comply with AAMI SP10	Comply with AAMI SP10
	Comply with ISO 9919	Comply with ISO 9919
	Comply with IEC 60601-1-8	Comply with IEC 60601-1-8

The proposed devices, A Series / Q Series Patient Monitors, AnyView A8, AnyView A6, AnyView A5, AnyView A3, Q2, Q3, Q4, Q5, Q6 and Q7, are determined to be Substantially Equivalent (SE) to the predicate devices, as identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 18, 2014

Guangdong Biolight Meditech Co., Ltd.
C/O Ms. Diana Hong
General Manager
P.O. Box 120-119
Shanghai, 200120 CH

Re: K131898
Trade/Device Name: A series and Q Series Patient Monitors
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (Without Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: January 3, 2014
Received: January 8, 2014

Dear Ms. Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131898

Device Name: Patient Monitors

Indications for Use: Patient monitors are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR), Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Carbon dioxide (CO2), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Cerebral State Index (CSI), Bispectral Index (BIS), Total Hemoglobin(SpHb), Carboxyhemoglobin (SpCO), and Methemoglobin(SpMet).

The arrhythmia detection, ST segment analysis only applied to a single adult patient.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician.

It is not intended for helicopter transport, hospital ambulance, or home use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Digitally signed by Owen P. Faris -S
Date: 2014.02.18 13:29:35 -05'00'